IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., et al., Plaintiffs, v. LUPIN LTD., et al., Defendants.	C.A. No. 09-037 (RBK) (JS) (CONSOLIDATED)

DECLARATION OF LESLIE SANDS

I, Leslie Sands, declare as follows:

1. I am the Director, Regulatory Affairs, of Lupin Pharmaceuticals, Inc. ("Lupin"). Among my responsibilities in this position is interacting with the Food and Drug Administration, including giving information to the FDA with respect to ANDAs filed by Lupin and communicating with the FDA about such issues as the contents of the package insert or label that will accompany a drug.

2. I have over 17 years in the pharmaceutical industry, and I have worked for Lupin as the Director of Regulatory Affairs for the past five years.

3. It was my understanding that the FDA requires the package insert for a generic pharmaceutical product to be almost identical to that of the brand drug, and that therefore Lupin could not modify even the results of tests of the brand drug which were included on the brand package insert. This understanding was shared by others at Lupin and at our parent company Lupin Ltd. responsible for regulatory matters and for preparing the package inserts for review and approval by the FDA.

4. It was also my understanding that the FDA was aware that the information on the package inserts referred to tests of the brand products. Since we submitted to the FDA

bioequivalence tests and other tests included in our ANDAs, the FDA knew when the test results on the proposed package insert were not from tests of the generic product, and that the test results of the generic product could differ to a certain extent from those of the brand.

5. Last week, I called Martin Shimer of the FDA; I believe his title at the FDA is Branch Chief for Regulatory. I asked him whether Lupin could substitute the test results for its product, for the brand test results included in our approved label.

6. Somewhat to my surprise, Mr. Shimer informed me it might be permissible for Lupin to substitute its own test results for those of the brand product on the label. However, he told me that we could not substitute the test results of our metformin product on our label, because the tests we had conducted – measuring mean T_{max} after a single dose administered after dinner or after breakfast – were not the same tests as the test on the label which measured the mean T_{max} after administration of multiple doses over several weeks. Therefore, since we did not have results of the same test, we could not make any changes and should continue to include test results for the brand product.

7. I also asked Mr. Shimer whether, if it was not possible to include the tests of Lupin's product, we could state explicitly on the label that the product tested was the brand product, to clarify that these were not the results of tests of Lupin's product. Mr. Shimer, speaking for the FDA, answered that we could not do this.

I declare under penalty of perjury that the foregoing statements are true and correct.

Dated: December 13, 2011

Leslie Sands